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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,717	04/13/2000	Katsuya Daimon	472552000100	7198

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1656

DATE MAILED: 01/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/548,717

Applicant(s)

DAIMON ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' response to restriction requirement (Paper No. 7). Applicant's election without traverse of Group I (claims 1-22) in Paper No. 7 is acknowledged.
2. The Information Disclosure Statement (Paper No. 4) filed on August 24, 2000, has been entered and considered.
3. The disclosure is objected because of the following informalities:
  - a) in claim 1 and 8 the measuring units for volume is mm<sup>3</sup>/ g, instead of ml/g.Correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- a) Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

Method claims require a last step or phrase in the last step that states the accomplishment of the goals for the method, which were stated in the method's preamble. Claim 1 lacks such a last step (how the extraction of nucleic acids is facilitated) and is confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. App. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

- b) Claims 9 and 14 are rejected under 35 U.S.C. § 112, second paragraph, as

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being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9 and 14 are confusing for referring to the subject matter in the term "and/or". Thus it is unclear how the claims can simultaneously encompass all of these limitations. The claims should refer to the subject matter in the alternative only, the replacement of the term "and/or" with "or" or the addition of dependent claims are suggested.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Uematsu et al. (USPN. 5,945,525).

Uematsu et al. teach a method for isolating nucleic acids using silica-coated magnetic particles wherein Uematsu et al. disclose that the method comprises

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(i) nucleic acid binding particulate carrier (silica coated magnetic particle) with a particle diameter of about 0.5 to about 15 $\mu$ m, a pore diameter of 0.1 to about 60nm, a pore volume of 0.01 to about 1.5ml/g and a specific surface area of about 100 to about 800 m<sup>2</sup>/g (see column 3, lines 44-65);

(ii) the magnetic silica particulate carrier contains superparamagnetic metal oxide (iron oxide) (see column 3, lines 44-47 and 53-54) and the metal oxide contained an amount of about 10 to about 60% by weight (see column 3, lines 56-58);

(iii) the method includes (a) mixing the material containing nucleic acids with the nucleic acid-binding particulate carrier so as to facilitate binding the nucleic acids to the particulate carrier; (b) separating a composite of the nucleic acids and the particulate carrier from the mixture in step (a) to remove contaminants; and eluting the nucleic acids from the composite of the nucleic acids and the particulate (see column 3, lines 66-67 and column 4, lines 1-11);

(iv) the material containing nucleic acids was a biological material containing DNA, RNA, protein etc., and the biological material include a bacteriophage, virus and bacteria (see column 7, lines 32-40);

(v) the method contains chaotropic substance selected from a group consisting of guanidine salt sodium iodide, potassium iodide, sodium (iso)thiocyanate, urea and the like (see column 7, lines 41-50);

(vi) wash buffer (first wash buffer) contains chaotropic substance (guanidine thiocyanate) and the elution buffer (second wash solution) contains alcohol (70%) (see column 8, lines 24-46);

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(vii) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction (PCR) or nucleic acid sequence based amplification (NASBA) and detecting the target by nucleic acid hybridization assay (see column 8, lines 57-67 and column 9, lines 1-10).

Thus the disclosure of Uematsu et al. meets the limitations in the instant claims.


No claims are allowable.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
January 10, 2002

  
**JEFFREY FREDMAN**  
**PRIMARY EXAMINER**